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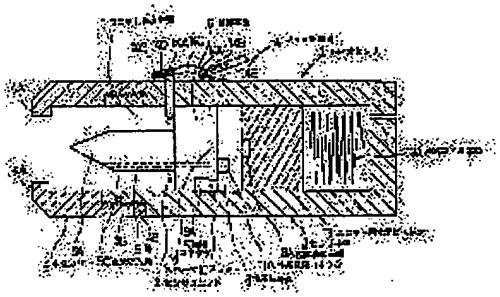
(54) BIOSENSOR

(57)Abstract:
PROBLEM TO BE SOLVED: To provide a biosensor capable of simplifying a measurement operation and surely measuring a component density.
SOLUTION: A sensor unit 2 is inserted through a compression coil spring 13A inside a sensor main body 3, the sensor unit 2 is locked by a switching mechanism 14 and a main body cover 4 is mounted in the state of inserting the sensor unit 2 inside the sensor main body 3. Thus, the sensor unit 2 is prevented from being fired by the switching mechanism 14. A blood introduction path 5C is formed at the needle 5 of the sensor unit 2 and the blood introduction path 5C is continued to a space inside the slit 10 of a spacer 7. A counter electrode and an action electrode are arranged so as to face each other in the space. Thus, by a simple operation, blood introduced from the needle 5 is simultaneously brought into contact with the counter electrode and the action electrode and the sure measurement of a substrate density is made possible.



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CLAIMS

[Claim(s)]
[Claim 1] The biosensor characterized by having the sensor unit which has the extraction needle equipped with the sample liquid installation way, the sample liquid installation space which was open for free passage on this sample liquid installation way, and the counter electrode and operation pole which were established in the opposed face of this sample liquid installation space.
[Claim 2] The body of a sensor with which the spring which energizes the unit insertion space which inserts said sensor unit, and said sensor unit has been arranged, A stop means to stop said sensor unit where said sensor unit is resisted and inserted in the energization force of said spring from opening of said unit insertion space to a predetermined location, The biosensor according to claim 1 characterized by having body covering which makes only the extraction needle of said sensor unit project to the method of outside when it is attached in the opening side of said unit insertion space of said sensor unit and the stop condition of said stop means is canceled.
[Claim 3] The biosensor according to claim 2 characterized by arranging the connector area material which contacts according to an individual on the counter electrode and operation pole of this sensor unit, respectively after the extraction needle of said sensor unit has projected to the wall of said body covering or said body of a sensor.
[Claim 4] The biosensor according to claim 1 to 3 characterized by forming in said operation pole the enzyme fixed layer containing the enzyme which produces the substrate and enzyme reaction in sample liquid or this enzyme, and a mediator.
[Claim 5] The end of said spring is a biosensor according to claim 1 to 4 characterized by being fixed to said body side of a sensor, and fixing to the other end of said spring the piston for unit immobilization which equips with said sensor unit removable.

[Translation done.]

DETAILED DESCRIPTION

[Detailed Description of the Invention]
[0001]
[Field of the Invention] This invention relates to the biosensor which performs density measurement of the various components in blood in more detail about a biosensor.
[0002]
[Description of the Prior Art] Conventionally, what predetermined distance was separated [what] and arranged the operation pole (anode) and the counter electrode (cathode), for example on the single substrate as a biosensor which measures the constituent concentration in blood is known. The enzyme which makes a predetermined component cause an enzyme reaction is fixed by the front face of an operation pole. In order to measure the constituent concentration in blood using such a biosensor, the procedure explained below performs. First, a skin front face is damaged with the needle with which the blood extraction instrument prepared separately is equipped, and the blood which comes out on a skin front face is extracted using a blood extraction instrument. Next, with a blood extraction instrument, the extracted blood is dropped so that the operation pole and counter electrode of a biosensor may be contacted. Thus, the concentration of the component in blood which causes an enzyme reaction is decided by measuring the current value to which blood impresses a predetermined electrical potential difference between two electrodes, and flows between two electrodes where two electrodes are contacted.
[0003]
[Problem(s) to be Solved by the Invention] However, the technique of carrying blood exactly on a biosensor was required of the above-mentioned conventional biosensor. Moreover, in the conventional biosensor, there was a possibility of changing a measurement current value with the amount of the blood in contact with two electrodes. In addition, although the thing of a configuration of making the operation pole and counter electrode which were prepared in the separate substrate counter besides the biosensor of a configuration of having described above, and introducing blood to between two electrodes using capillarity was proposed, at the point using a blood extraction instrument, it was the same as that of the above-mentioned biosensor, and was what needs actuation of a blood extraction process, and a measurement process and at least 2 processes of **. When using a blood extraction instrument especially, the blood more than the amount needed for measurement was required.
[0004] This Object of the Invention is simple for measurement actuation, and it is in the point what kind of means should be provided for obtaining the biosensor which moreover makes positive component density measurement possible.
[0005]
[Means for Solving the Problem] Invention according to claim 1 is characterized by having the sensor unit which has the extraction needle equipped with the sample liquid installation way, the sample liquid installation space which was open for free passage on this sample liquid installation way, and the

counter electrode and operation pole which were established in the opposed face of this sample liquid installation space.

[0006] In invention according to claim 1, since the sample liquid installation space in which the counter electrode and the operation pole were established from the extraction needle is open for free passage, it can measure simply only by extracting sample liquid directly from an extraction needle. Moreover, since sample liquid is quantitatively [a little and] extractable by setting up the volume of sample liquid installation space, it can measure with high precision.

[0007] The body of a sensor with which the spring which energizes the unit insertion space where invention according to claim 2 inserts said sensor unit, and said sensor unit has been arranged, A stop means to stop said sensor unit where said sensor unit is resisted and inserted in the energization force of said spring from opening of said unit insertion space to a predetermined location, When it is attached in the opening side of said unit insertion space of said sensor unit and the stop condition of said stop means is canceled, it is characterized by having body covering which makes only the extraction needle of said sensor unit project to the method of outside.

[0008] In invention according to claim 2, if the sensor unit stopped by the stop means in the predetermined location of the unit insertion space of the body of a sensor cancels a stop condition, the energization force of a spring extrudes and only an extraction needle can extract a projection and sample liquid to the method of outside.

[0009] Invention according to claim 3 is in the condition which the extraction needle of said sensor unit projected to the wall of said body covering or said body of a sensor, and is characterized by arranging the connector area material which contacts according to an individual on the counter electrode and operation pole of this sensor unit, respectively. In invention according to claim 3, it is set up so that measurement of the substrate concentration in sample liquid may begin, after the extraction needle has projected from body covering. For this reason, density measurement becomes possible automatically in the phase which canceled the stop condition of a stop means.

[0010] Invention according to claim 4 is characterized by forming in said operation pole the enzyme fixed layer containing the enzyme which produces the substrate and enzyme reaction in sample liquid or this enzyme, and a mediator. In invention according to claim 4, a substrate can decide substrate concentration by measuring the current which flows between a lifting, a counter electrode, and operation poles in an enzyme reaction in response to the catalysis of an enzyme. Moreover, in the enzyme fixed layer containing an enzyme and a mediator, in case the enzyme which the substrate was oxidized, for example and changed to the reduction type returns to the original oxidization mold, a mediator takes an electron from an enzyme and it becomes a reduction type mediator, and according to electrode reaction, this reduction type mediator gives an electron to an electrode, and, thereby, returns to the original oxidization mold mediator. That is, if a substrate exists in the enzyme fixed layer containing an enzyme and a mediator, an electron will move to an electrode mediating an enzyme and a mediator, and the current according to substrate concentration will flow. Therefore, substrate concentration can be decided if this current is detected.

[0011] Invention according to claim 5 is characterized by fixing the end of said spring to said body side of a sensor, and fixing to the other end of said spring the piston for unit immobilization which equips with said sensor unit removable. In invention according to claim 5, since a sensor unit is fixable to the piston for unit immobilization, it can prevent that a sensor unit is discharged from the body of a sensor also in the condition of having not equipped the body of a sensor with body covering.

[0012]

[Embodiment of the Invention] It explains based on the operation gestalt which shows the detail of the biosensor concerning this invention hereafter to a drawing.

[0013] For the cross-section explanatory view of the biosensor which drawing 1 and drawing 2 require for this operation gestalt, and drawing 3 , the decomposition perspective view of a sensor unit and

drawing 4 are [the partial cross-section perspective view of body covering and drawing 6 of the sectional view of a sensor unit and drawing 5] representative circuit schematics.

[0014] The configuration of the biosensor concerning this operation gestalt is explained. As shown in drawing 1 and drawing 2 , the profile configuration of the biosensor 1 is carried out from the sensor unit 2, the body 3 of a sensor, and the body covering 4. The description of the configuration of this biosensor 1 is a point which has the composition of loading the body 3 of a sensor with the sensor unit 2, and attaching the body covering 4. For this reason, with this operation gestalt, exchange of the sensor unit 2 becomes easy.

[0015] Hereafter, the configuration of the sensor unit 2 is explained to a detail. As shown in drawing 1 - drawing 4 , the sensor unit 2 is constituted combining the needle 5, the counter electrode base 6, the spacer 7, and the operation pole base 8 as a blood collecting needle in one.

[0016] Blood installation way 5C penetrated towards end face 5B from near tip (tip) 5A is formed by the configuration of a needle 5 like the well-known hypodermic needle. Although the diameter of this needle 5 is about 1mm and the diameter of blood installation way 5C is about 0.2mm, all over drawing, the needle 5 is relatively drawn on the thick path for the facilities of explanation. Moreover, flat-surface 5D for positioning is formed in the circumferential side face of the end face 5B approach of this needle 5 along the die-length direction. If it puts in another way, the cross section of the part of the end face 5B approach of a needle 5 serves as a configuration of the circle which cut off a part of arc. Furthermore, the die length of a needle 5 is set up comparatively short, in order for what is necessary to be to just be shallowly stuck from the skin front face of the body so that a postscript may be carried out.

[0017] Next, the configuration of the counter electrode base 6 is explained. The counter electrode base 6 becomes with an ingredient with electric insulation, and as shown in drawing 3 , it is formed in the cylindrical container configuration. That is, needle insertion opening 6A for inserting in densely end face 5B of the above-mentioned needle 5 is formed in the front face of this counter electrode base 6. And as shown in drawing 4 , blood installation way 5C of a needle 5 and inlet 6D open for free passage are formed in bottom plate 6C of the counter electrode base 6. In addition, sign 6B shown in drawing 3 is a plane insertion opening side attachment wall corresponding to flat-surface 5D for positioning of a needle 5. It sets in such structure, and end face 5B of a needle 5 is being equipped with and fixed by needle insertion opening 6A. Moreover, it is formed in the predetermined location so that the counter electrode (cathode) 9 which becomes with an electrode material suitably may be exposed to the rear face of the counter electrode base 6. Furthermore, connector (contact electrode for counter electrodes) 9A for counter electrodes electrically connected with the counter electrode 9 is formed in the predetermined location of the peripheral surface of the counter electrode base 6.

[0018] The spacer 7 is formed in the disc-like configuration with the same path dimension as the counter electrode base 6 which became with the ingredient with electric insulation and was described above. And the slit 10 cut and lacked towards the direction of a core of a disk is formed in this spacer 7. This spacer 7 is being pasted up and fixed so that a slit 10 may attend the rear face of the above-mentioned counter electrode base 6 at the counter electrode 9 of the counter electrode base 6.

[0019] Next, the configuration of the operation pole base 8 is explained. The operation pole base 8 has the approximate circle plate structure of the same path dimension as the above-mentioned spacer 7 and the above-mentioned counter electrode base 6. It is formed with the ingredient in which this operation pole base 8 also has electric insulation. Moreover, as shown in drawing 3 , the operation pole 11 which becomes with a predetermined electrode material is formed in the predetermined location of the front face of this operation pole base 8. As for the point of this operation pole 11, the enzyme fixed layer 12 which comes to fix glucose oxidase (GOD) and cow serum albumin (BSA) is formed. Furthermore, connector (contact electrode for operation poles) 11A for operation poles connected electrically is formed in the operation pole 11 at the peripheral surface of the operation pole base 8. Moreover, as shown in drawing 4 , locating-lug 8A which projects back is formed in the center of a rear face of the

operation pole base 8. This locating-lug 8A is seen from back, and a single-character configuration, its cross configuration, etc. are good suitably at the projection of a configuration. Such an operation pole base 8 of a configuration is being pasted up and fixed so that the operation pole 11 and the enzyme fixed layer 12 may attend the rear face of the above-mentioned spacer 7 at the slit 10 of a spacer 7.

[0020] The mutual physical relationship of these needles 5, the counter electrode base 6, a spacer 7, and the operation pole base 8 is explained below. When a needle 5 is inserted in the counter electrode base 6 so that insertion opening side-attachment-wall 6B and ** in needle insertion opening 6A of the counter electrode base 6 may lap with flat-surface 5D for positioning formed in the peripheral surface of end face 5B of a needle 5, both needle 5 and counter electrode base 6 fit in densely, and they are positioned. At this time, it is set up so that blood installation way 5C of a needle 5 and inlet 6D of the counter electrode base 6 may be open for free passage. Moreover, as described above, the operation pole 11 (the enzyme fixed layer 12 is included) formed in the counter electrode 9, inlet 6D, and the operation pole base 8 which were formed in the counter electrode base 6 is set up so that the space formed to the slit 10 formed in the spacer 7 may be attended. For this reason, a counter electrode 9 and the operation pole 11 (the enzyme fixed layer 12 is included) counter through the space in a slit 10. In addition, the space in the slit 10 pinched in the base (rear face) of the counter electrode base 6 and the front face of the operation pole base 8 is set to blood installation space 10A. And it is set up so that connector 9A for counter electrodes formed in the peripheral surface of the counter electrode base 6, connector 11A for operation poles formed in the peripheral surface of the operation pole base 8, and ** and the location which shifted in the circumference direction the degree of predetermined angle mutually may be made. In addition, locating-lug 8A formed in the center of a rear face of the operation pole base 8 has a positioning function to the member by the side of the body 3 of a sensor which carries out a postscript.

[0021] Next, the configuration of the body 3 of a sensor equipped with the above-mentioned sensor unit 2 is explained. The body 3 of a sensor has the approximate circle cylinder container-like structure where unit insertion space 3A of the shape of a cylindrical shape which can insert the sensor unit 2 in shaft orientations was formed, as shown in drawing 1 and drawing 2 . in addition, the diameter of unit insertion space 3A -- the outer diameter of the sensor unit 2, and abbreviation -- similarly it is set up. Moreover, the approximate circle column-like piston 13 for unit immobilization can insert a cross direction now in this unit insertion space 3A, enabling free sliding. That is, the outer diameter of this piston 13 for unit immobilization is also set as the outer diameter and abbreviation identitas of the sensor unit 2. And the end of compression coil spring 13A is being fixed in the center of a base within the body 3 of a sensor. Moreover, the other end of compression coil spring 13A is being fixed in the center of a rear face of the above-mentioned piston 13 for unit immobilization. Furthermore, fitting and location notch 13B to fix are formed in the front face of the piston 13 for unit immobilization in locating-lug 8A of the above-mentioned operation pole base 8. In addition, although not illustrated, it engages with the wall of the piston 13 for unit immobilization, and the body 3 of a sensor mutually, and the rotation prevention device which can slide only in the die-length direction is established so that the piston 13 for unit immobilization may not rotate a shaft as a core within unit insertion space 3A. Screw section 3B which screw section 4B of the body covering 4 which carries out a postscript screws is formed in the lateral surface of opening of the front end of the body 3 of a sensor. Moreover, the switch mechanism 14 is formed near the opening of the body 3 of a sensor. The lead wire 16A and 16B connected to contact bowl 17for counter electrodes A of the body covering 4 and the body covering 4 later mentioned at the time of screwing and contact bowl 17B for operation poles, respectively is formed in the body 3 of a sensor.

[0022] Hereafter, the configuration of a switch mechanism 14 is explained using drawing 1 R> 1 and drawing 2 . First, piece of two pieces of bearings which carry out phase opposite 14A prepared so that this switch mechanism 14 might project in the lateral surface of the body 3 of a sensor, Pivotable support shaft 14B constructed among these two pieces of piece of bearing 14A, Stop pin 14D which engages

with the front end side of drive lever 14C by which pars intermedia was supported pivotably by this pivotable support shaft 14B, and this drive lever 14C, and penetrates the side attachment wall of the body 3 of a sensor, and appears frequently in unit insertion space 3A, twisted coil spring 14E energized so that drive lever 14C may fall in front -- since -- the profile configuration is carried out. Moreover, guide hole 14G are formed in the anterior part of drive lever 14C along with the longitudinal direction. And guide shaft 14H are prepared in the upper limit of the above-mentioned stop pin 14D. These guide shaft 14H are being engaged free [sliding] to guide hole 14G. Stop pin 14D appears frequently to unit insertion space 3A in connection with the drive of drive lever 14C. At this time, along with guide hole 14G, guide shaft 14H slide and are guided. In addition, when this stop pin 14D inserts the sensor unit 2 in unit insertion space 3A of the body 3 of a sensor, it has the function to prevent that stop the front end of the counter electrode base 6, and the sensor unit 2 jumps out ahead.

[0023] Next, the configuration of the body covering 4 is explained using drawing 1 , drawing 2 , and drawing 5 . The body covering 4 is formed in the tubing configuration for example, with the resin ingredient which has insulation electrically. Contact bowl 17for counter electrodes A which the sensor unit 2 projects and connector 9for counter electrodes A and connector 11A for operation poles sometimes connect, respectively, and contact bowl 17B for operation poles are prepared in the interior of the body covering 4, and contact bowl 17for counter electrodes A and contact bowl 17B for operation poles are connected with the lead wire 16A and 16B of the body 3 of a sensor, respectively at the time of screwing with the body 3 of a sensor, and the body covering 4. moreover, opening of the body covering 4 front end -- the inside -- turning -- a collar -- flange 4A of a ** goes around and is formed. For this reason, as for the inside diameter of flange 4A, the inside diameter twist of the part of that back (back) is short. Moreover, screw section 3B of the above-mentioned body 3 of a sensor and screw section 4B to screw are formed in the opening wall of the back end of the body covering 4. In addition, in the condition of having screwed the screw sections of the body 3 of a sensor, and the body covering 4, it is set up so that the walls of the body 3 of a sensor and the body covering 4 may become flat-tapped. That is, except for the part of flange 4A of the body covering 4, and screw section 4B, the inside diameter of the body 3 of a sensor and the body covering 4 is set up identically. For this reason, where it contains the sensor unit 2 to unit insertion space 3A of the body 3 of a sensor and the body covering 4 is constructed on the body 3 of a sensor, even when the sensor unit 2 moves forward to max, in order that the front end side periphery section may **** the counter electrode base 6 to flange 4A, only a needle 5 projects from body covering 4 front face.

[0024] Here, the sensor unit 2 supplements with the configuration of the body covering 4 and the sensor unit 2 using drawing 2 which shows the condition of having moved forward to max. If stop pin 14D sinks from the internal surface of the body 3 of a sensor with actuation of a switch mechanism 14, the front face of the counter electrode base 6 of the unit sensor 2 **** to flange 4A according to the energization force of compression coil spring 13A. At this time, it prevents that stop pin 14D projects in unit insertion space 3A again. That is, where the sensor unit 2 is extruded to flange 4A, it is set up so that the tip of stop pin 14D may contact the peripheral surface of the piston 13 for unit immobilization. Moreover, in the condition that the sensor unit 2 was extruded to flange 4A, connector 9A for counter electrodes of the sensor unit 2 is connected with contact bowl 17A for counter electrodes, and connector 11A for operation poles is connected with contact bowl 17B for operation poles. In addition, contact bowl 17A for these counter electrodes and contact bowl 17B for operation poles are formed with an electrode material, and are connected to lead wire 16A and 16B, respectively. These lead wire 16A and 16B is connected so that the body covering 4 may be penetrated from the outside of the body covering 4 and each end section may attain even a contact bowl. In addition, the other end of these lead wire 16A and 16B is connected to the electrical-potential-difference impression circuit 18 and the amperometry circuit 19 which carry out a postscript.

[0025] Next, it explains using the equal circuit which shows the circuitry of the blood sugar level gaging

system in the biosensor 1 of this operation gestalt to drawing 7 . As shown in this drawing, the counter electrode 9 is connected to the electrical-potential-difference impression circuit 18 and the amperometry circuit 19 through connector 9for counter electrodes A, contact bowl 17for counter electrodes A, and lead-wire 16A. Moreover, the operation pole 11 (the enzyme fixed layer 12 is included) is connected to the electrical-potential-difference impression circuit 18 and the amperometry circuit 19 through connector 11for operation poles A, contact bowl 17for operation poles B, and lead-wire 16B. Furthermore, the amperometry circuit 19 is connected to the operation means 20 and the display means 21. In addition, the amperometry circuit 19 fills a sample between a counter electrode 9 and the operation pole 11 by the electrical-potential-difference impression circuit 18, and after impression of an electrical potential difference is started and carrying out predetermined time progress, it is set up so that a current value may be measured. Moreover, from electrical-potential-difference impression initiation, after [still longer] carrying out time amount progress, the electrical-potential-difference impression circuit 18 is set up so that electrical-potential-difference impression may be stopped.

[0026] Next, the operating instructions of the biosensor 1 of this operation gestalt, and an operation and actuation are explained. First, it fixes by inserting locating-lug 8A formed in the rear face of the operation pole base 8 of the sensor unit 2 in location notch 13B of the piston 13 for unit immobilization in which the sensor unit 2 was formed by the body 3 of a sensor. Since it is set up so that it may not rotate in the body 3 of a sensor as the piston 13 for unit immobilization was described above at this time, the sensor unit 2 fixed to the piston 13 for unit immobilization does not rotate, either. Subsequently, actuation which resists the energization force of compression coil spring 13A, and pushes in the sensor unit 2 in unit insertion space 3A is performed. When the back end of the piston 13 for unit immobilization is located ahead of stop pin 14D at this time, it is necessary to change stop pin 14D into the condition of sinking from the wall of the body 3 of a sensor, by what (for the back end section of drive lever 14C to be turned and pushed on the body 3 of a sensor) drive lever 14C is operated for. And if the front end of the counter electrode base 6 of the sensor unit 2 progresses behind stop pin 14D, since the energization force of twisted coil spring 14E is transmitted to stop pin 14D through drive lever 14C, it projects in unit insertion space 3A. Thus, when stop pin 14D projects in unit insertion space 3A, the front end of the sensor unit 2 is stopped by stop pin 14D, and it is set where it is prevented that the sensor unit 2 jumps out ahead.

[0027] Next, the case where the blood sugar level is measured using the biosensor 1 in the condition that the sensor unit 2 was set as described above is explained. First, opening of the body covering 4 of a biosensor 1 is applied to the skins, such as people's arm, and the back end section of drive lever 14C of a switch mechanism 14 is turned to the outer wall of the body 3 of a sensor, and is pressed down. Consequently, drive lever 14C rotates in the direction of the clockwise rotation in drawing, turns stop pin 14D to a way outside the body 3 of a sensor, and pulls up it. When the tip of stop pin 14D sinks from the wall of the body 3 of a sensor, the sensor unit 2 jumps out [in / in the front end side of the counter electrode base 6 / flange 4A] ahead according to the energization force of compression coil spring 13A. At this time, only a needle 5 projects from opening of the body covering 4, pokes on the skin, and damages ******** and a hypodermic capillary. In connection with this, blood is introduced by capillarity in blood installation space 10A through blood installation way 5C of a needle 5, and inlet 6D of the counter electrode base 6. At this time, connector 9for counter electrodes A and connector 11A for operation poles are connected to contact bowl 17for counter electrodes A, and contact bowl 17B for operation poles, respectively, and the predetermined electrical potential difference is impressed from the electrical-potential-difference impression circuit 18 between the counter electrode 9 and the operation pole 11. Then, the current according to the glucose concentration in blood (minding a mediator, when the mediator is included), i.e., the blood sugar level, flows between a counter electrode 9 and the operation pole 11 through the dissolved oxygen by which the glucose in blood is contained in a lifting and the enzyme fixed layer 12 by operation of the enzyme fixed layer 12 in an enzyme reaction (reaction

for which a glucose oxidizes) and which is an electron acceptor. After carrying out impression initiation of the electrical potential difference between an electrode 9 and 11 from the electrical-potential-difference impression circuit 18, the current value according to the above-mentioned blood sugar level can be measured by carrying out predetermined time progress and performing an amperometry in the amperometry circuit 19. In addition, since the current after going through fixed time amount after electrical-potential-difference impression is proportional to the glucose concentration of a certain density range, by inputting the proportionality coefficient into the operation means 20 beforehand, it can convert a current value into concentration and can display the blood sugar level on the display means 21. In addition, after measurement of such the blood sugar level is performed, and predetermined time passes further, electrical-potential-difference impression of the electrical-potential-difference impression circuit 18 stops.

[0028] Thus, what is necessary is to remove the body covering 4 from the body 3 of a sensor, and just to remove the sensor unit 2 from the piston 13 for unit immobilization subsequently, after measurement of the blood sugar level is completed. What is necessary is again, just to repeat the actuation which changed and described the sensor unit 2 above, when measuring the blood sugar level.

[0029] With this operation gestalt, since blood installation space 10A can set it as the predetermined volume, it is very little, and since it ends, and the amount of the blood which measurement takes does not have the problem of taking blood too much unfairly and can collect blood quantitatively (since the space volume of the path which introduces blood may be very small), a generating current can also be measured quantitatively and it can measure [regularity and] the blood sugar level for it with high precision. Moreover, since what is necessary is just to stab with a needle 5, the amount of the bleeding from the skin can be controlled. Moreover, with this operation gestalt, there is an advantage that it can carry out at installation, measurement, and one process of blood, without needing a blood extraction instrument. Furthermore, in order to introduce blood between a counter electrode 9 and the operation pole 11 using capillarity, there is an advantage that measurement can be ensured.

[0030] As mentioned above, although this operation gestalt was explained, various kinds of modification which is not limited to this and accompanies the summary of a configuration is possible for this invention. For example, although glucose oxidase was used as an enzyme with the above-mentioned operation gestalt, in order to perform density measurement, such as other components in blood, a metaphor lactic acid, alcohol, cholesterol, and a uric acid, it is easy to be natural also as a configuration which fixed other enzymes. Moreover, it is good also as a configuration which contains a mediator in the above-mentioned enzyme fixed layer 12. Furthermore, although considered as the cylindrical shape-like body 3 of a sensor with the above-mentioned operation gestalt, it is easy to be natural [a cross-section configuration] also as a configuration which is not a circle. The contact bowl which contacts each connector formed in the peripheral surface of the sensor unit 2 further again is good also as a configuration formed in the body [not the body covering 4 but] 3 side of a sensor.

[0031] Furthermore, although the electrode in connection with measurement of constituent concentration was two, a counter electrode 9 and the operation pole 11 (an enzyme fixed layer is included), with the above-mentioned operation gestalt, it is good like the modification shown in drawing 7 also as a configuration which forms a reference electrode 22 near the operation pole 11 of the operation pole base 8. 22in drawing 7 A is the connector for reference electrodes which was formed in the peripheral surface of the operation pole base 8 and which was connected to the reference electrode 22. In addition, what is necessary is to form the contact bowl for reference electrodes in contact with connector 22A for reference electrodes in the body covering 4 side, and just to consider as the circuitry which added the reference electrode 22 in this modification, while adding a reference electrode 22 in this way. Other configurations are the same as that of the above-mentioned operation gestalt. Furthermore, as shown in drawing 8 , it can also consider as the configuration which added the enzyme non-holding operation pole 23 to the configuration of the modification shown in drawing 7 . Thus, it becomes possible to consider a

configuration equipped with the enzyme non-holding operation pole 23, then the effect by the active jamming current by the uric acid, and to perform high measurement of precision more. Moreover, the active jamming current by an ascorbic acid etc. can also be controlled by using the operation pole 11 as the carbon containing platinum or a rhodium.

[0032]

[Effect of the Invention] Measurement actuation can be simplified, while the amount of the blood used for measurement is reducible according to this invention so that clearly from the above explanation. And according to this invention, the effectiveness of realizing the biosensor which makes positive component density measurement possible is done so.

[Translation done.]

JAPANESE [JP,09-285459,A]

CLAIMS DETAILED DESCRIPTION TECHNICAL FIELD PRIOR ART EFFECT OF THE INVENTION TECHNICAL PROBLEM MEANS DESCRIPTION OF DRAWINGS DRAWINGS

[Translation done.]

PRIOR ART

[Description of the Prior Art] Conventionally, what predetermined distance was separated [what] and arranged the operation pole (anode) and the counter electrode (cathode), for example on the single substrate as a biosensor which measures the constituent concentration in blood is known. The enzyme which makes a predetermined component cause an enzyme reaction is fixed by the front face of an operation pole. In order to measure the constituent concentration in blood using such a biosensor, the procedure explained below performs. First, a skin front face is damaged with the needle with which the blood extraction instrument prepared separately is equipped, and the blood which comes out on a skin front face is extracted using a blood extraction instrument. Next, with a blood extraction instrument, the extracted blood is dropped so that the operation pole and counter electrode of a biosensor may be contacted. Thus, the concentration of the component in blood which causes an enzyme reaction is decided by measuring the current value to which blood impresses a predetermined electrical potential difference between two electrodes, and flows between two electrodes where two electrodes are contacted.

[Translation done.]

EFFECT OF THE INVENTION

[Effect of the Invention] Measurement actuation can be simplified, while the amount of the blood used for measurement is reducible according to this invention so that clearly from the above explanation. And according to this invention, the effectiveness of realizing the biosensor which makes positive component density measurement possible is done so.

[Translation done.]

TECHNICAL PROBLEM

[Problem(s) to be Solved by the Invention] However, the technique of carrying blood exactly on a biosensor was required of the above-mentioned conventional biosensor. Moreover, in the conventional biosensor, there was a possibility of changing a measurement current value with the amount of the blood in contact with two electrodes. In addition, although the thing of a configuration of making the operation pole and counter electrode which were prepared in the separate substrate counter besides the biosensor of a configuration of having described above, and introducing blood to between two electrodes using capillarity was proposed, at the point using a blood extraction instrument, it was the same as that of the above-mentioned biosensor, and was what needs actuation of a blood extraction process, and a measurement process and at least 2 processes of **. When using a blood extraction instrument especially, the blood more than the amount needed for measurement was required.
[0004] This Object of the Invention is simple for measurement actuation, and it is in the point what kind of means should be provided for obtaining the biosensor which moreover makes positive component density measurement possible.

[Translation done.]

MEANS

[Means for Solving the Problem] Invention according to claim 1 is characterized by having the sensor unit which has the extraction needle equipped with the sample liquid installation way, the sample liquid installation space which was open for free passage on this sample liquid installation way, and the counter electrode and operation pole which were established in the opposed face of this sample liquid installation space.

[0006] In invention according to claim 1, since the sample liquid installation space in which the counter electrode and the operation pole were established from the extraction needle is open for free passage, it can measure simply only by extracting sample liquid directly from an extraction needle. Moreover, since sample liquid is quantitatively [a little and] extractable by setting up the volume of sample liquid installation space, it can measure with high precision.

[0007] The body of a sensor with which the spring which energizes the unit insertion space where invention according to claim 2 inserts said sensor unit, and said sensor unit has been arranged, A stop means to stop said sensor unit where said sensor unit is resisted and inserted in the energization force of said spring from opening of said unit insertion space to a predetermined location, When it is attached in the opening side of said unit insertion space of said sensor unit and the stop condition of said stop means is canceled, it is characterized by having body covering which makes only the extraction needle of said sensor unit project to the method of outside.

[0008] In invention according to claim 2, if the sensor unit stopped by the stop means in the predetermined location of the unit insertion space of the body of a sensor cancels a stop condition, the energization force of a spring extrudes and only an extraction needle can extract a projection and sample liquid to the method of outside.

[0009] Invention according to claim 3 is in the condition which the extraction needle of said sensor unit projected to the wall of said body covering or said body of a sensor, and is characterized by arranging the connector area material which contacts according to an individual on the counter electrode and operation pole of this sensor unit, respectively. In invention according to claim 3, it is set up so that measurement of the substrate concentration in sample liquid may begin, after the extraction needle has projected from body covering. For this reason, density measurement becomes possible automatically in the phase which canceled the stop condition of a stop means.

[0010] Invention according to claim 4 is characterized by forming in said operation pole the enzyme fixed layer containing the enzyme which produces the substrate and enzyme reaction in sample liquid or this enzyme, and a mediator. In invention according to claim 4, a substrate can decide substrate concentration by measuring the current which flows between a lifting, a counter electrode, and operation poles in an enzyme reaction in response to the catalysis of an enzyme. Moreover, in the enzyme fixed layer containing an enzyme and a mediator, in case the enzyme which the substrate was oxidized, for example and changed to the reduction type returns to the original oxidization mold, a mediator takes an electron from an enzyme and it becomes a reduction type mediator, and according to electrode reaction,

this reduction type mediator gives an electron to an electrode, and, thereby, returns to the original oxidization mold mediator. That is, if a substrate exists in the enzyme fixed layer containing an enzyme and a mediator, an electron will move to an electrode mediating an enzyme and a mediator, and the current according to substrate concentration will flow. Therefore, substrate concentration can be decided if this current is detected.

[0011] Invention according to claim 5 is characterized by fixing the end of said spring to said body side of a sensor, and fixing to the other end of said spring the piston for unit immobilization which equips with said sensor unit removable. In invention according to claim 5, since a sensor unit is fixable to the piston for unit immobilization, it can prevent that a sensor unit is discharged from the body of a sensor also in the condition of having not equipped the body of a sensor with body covering.

[0012]

[Embodiment of the Invention] It explains based on the operation gestalt which shows the detail of the biosensor concerning this invention hereafter to a drawing.

[0013] For the cross-section explanatory view of the biosensor which drawing 1 and drawing 2 require for this operation gestalt, and drawing 3 , the decomposition perspective view of a sensor unit and drawing 4 are [the partial cross-section perspective view of body covering and drawing 6 of the sectional view of a sensor unit and drawing 5] representative circuit schematics.

[0014] The configuration of the biosensor concerning this operation gestalt is explained. As shown in drawing 1 and drawing 2 , the profile configuration of the biosensor 1 is carried out from the sensor unit 2, the body 3 of a sensor, and the body covering 4. The description of the configuration of this biosensor 1 is a point which has the composition of loading the body 3 of a sensor with the sensor unit 2, and attaching the body covering 4. For this reason, with this operation gestalt, exchange of the sensor unit 2 becomes easy.

[0015] Hereafter, the configuration of the sensor unit 2 is explained to a detail. As shown in drawing 1 - drawing 4 , the sensor unit 2 is constituted combining the needle 5, the counter electrode base 6, the spacer 7, and the operation pole base 8 as a blood collecting needle in one.

[0016] Blood installation way 5C penetrated towards end face 5B from near tip (tip) 5A is formed by the configuration of a needle 5 like the well-known hypodermic needle. Although the diameter of this needle 5 is about 1mm and the diameter of blood installation way 5C is about 0.2mm, all over drawing, the needle 5 is relatively drawn on the thick path for the facilities of explanation. Moreover, flat-surface 5D for positioning is formed in the circumferential side face of the end face 5B approach of this needle 5 along the die-length direction. If it puts in another way, the cross section of the part of the end face 5B approach of a needle 5 serves as a configuration of the circle which cut off a part of arc. Furthermore, the die length of a needle 5 is set up comparatively short, in order for what is necessary to be to just be shallowly stuck from the skin front face of the body so that a postscript may be carried out.

[0017] Next, the configuration of the counter electrode base 6 is explained. The counter electrode base 6 becomes with an ingredient with electric insulation, and as shown in drawing 3 , it is formed in the cylindrical container configuration. That is, needle insertion opening 6A for inserting in densely end face 5B of the above-mentioned needle 5 is formed in the front face of this counter electrode base 6. And as shown in drawing 4 , blood installation way 5C of a needle 5 and inlet 6D open for free passage are formed in bottom plate 6C of the counter electrode base 6. In addition, sign 6B shown in drawing 3 is a plane insertion opening side attachment wall corresponding to flat-surface 5D for positioning of a needle 5. It sets in such structure, and end face 5B of a needle 5 is being equipped with and fixed by needle insertion opening 6A. Moreover, it is formed in the predetermined location so that the counter electrode (cathode) 9 which becomes with an electrode material suitably may be exposed to the rear face of the counter electrode base 6. Furthermore, connector (contact electrode for counter electrodes) 9A for counter electrodes electrically connected with the counter electrode 9 is formed in the predetermined location of the peripheral surface of the counter electrode base 6.

[0018] The spacer 7 is formed in the disc-like configuration with the same path dimension as the counter

electrode base 6 which became with the ingredient with electric insulation and was described above. And the slit 10 cut and lacked towards the direction of a core of a disk is formed in this spacer 7. This spacer 7 is being pasted up and fixed so that a slit 10 may attend the rear face of the above-mentioned counter electrode base 6 at the counter electrode 9 of the counter electrode base 6.

[0019] Next, the configuration of the operation pole base 8 is explained. The operation pole base 8 has the approximate circle plate structure of the same path dimension as the above-mentioned spacer 7 and the above-mentioned counter electrode base 6. It is formed with the ingredient in which this operation pole base 8 also has electric insulation. Moreover, as shown in drawing 3 , the operation pole 11 which becomes with a predetermined electrode material is formed in the predetermined location of the front face of this operation pole base 8. As for the point of this operation pole 11, the enzyme fixed layer 12 which comes to fix glucose oxidase (GOD) and cow serum albumin (BSA) is formed. Furthermore, connector (contact electrode for operation poles) 11A for operation poles connected electrically is formed in the operation pole 11 at the peripheral surface of the operation pole base 8. Moreover, as shown in drawing 4 , locating-lug 8A which projects back is formed in the center of a rear face of the operation pole base 8. This locating-lug 8A is seen from back, and a single-character configuration, its cross configuration, etc. are good suitably at the projection of a configuration. Such an operation pole base 8 of a configuration is being pasted up and fixed so that the operation pole 11 and the enzyme fixed layer 12 may attend the rear face of the above-mentioned spacer 7 at the slit 10 of a spacer 7.

[0020] The mutual physical relationship of these needles 5, the counter electrode base 6, a spacer 7, and the operation pole base 8 is explained below. When a needle 5 is inserted in the counter electrode base 6 so that insertion opening side-attachment-wall 6B and ** in needle insertion opening 6A of the counter electrode base 6 may lap with flat-surface 5D for positioning formed in the peripheral surface of end face 5B of a needle 5, both needle 5 and counter electrode base 6 fit in densely, and they are positioned. At this time, it is set up so that blood installation way 5C of a needle 5 and inlet 6D of the counter electrode base 6 may be open for free passage. Moreover, as described above, the operation pole 11 (the enzyme fixed layer 12 is included) formed in the counter electrode 9, inlet 6D, and the operation pole base 8 which were formed in the counter electrode base 6 is set up so that the space formed to the slit 10 formed in the spacer 7 may be attended. For this reason, a counter electrode 9 and the operation pole 11 (the enzyme fixed layer 12 is included) counter through the space in a slit 10. In addition, the space in the slit 10 pinched in the base (rear face) of the counter electrode base 6 and the front face of the operation pole base 8 is set to blood installation space 10A. And it is set up so that connector 9A for counter electrodes formed in the peripheral surface of the counter electrode base 6, connector 11A for operation poles formed in the peripheral surface of the operation pole base 8, and ** and the location which shifted in the circumference direction the degree of predetermined angle mutually may be made. In addition, locating-lug 8A formed in the center of a rear face of the operation pole base 8 has a positioning function to the member by the side of the body 3 of a sensor which carries out a postscript.

[0021] Next, the configuration of the body 3 of a sensor equipped with the above-mentioned sensor unit 2 is explained. The body 3 of a sensor has the approximate circle cylinder container-like structure where unit insertion space 3A of the shape of a cylindrical shape which can insert the sensor unit 2 in shaft orientations was formed, as shown in drawing 1 and drawing 2 . in addition, the diameter of unit insertion space 3A -- the outer diameter of the sensor unit 2, and abbreviation -- similarly it is set up. Moreover, the approximate circle column-like piston 13 for unit immobilization can insert a cross direction now in this unit insertion space 3A, enabling free sliding. That is, the outer diameter of this piston 13 for unit immobilization is also set as the outer diameter and abbreviation identitas of the sensor unit 2. And the end of compression coil spring 13A is being fixed in the center of a base within the body 3 of a sensor. Moreover, the other end of compression coil spring 13A is being fixed in the center of a rear face of the above-mentioned piston 13 for unit immobilization. Furthermore, fitting and location notch 13B to fix are formed in the front face of the piston 13 for unit immobilization in locating-lug 8A of the above-mentioned operation pole base 8. In addition, although not illustrated, it engages with the

wall of the piston 13 for unit immobilization, and the body 3 of a sensor mutually, and the rotation prevention device which can slide only in the die-length direction is established so that the piston 13 for unit immobilization may not rotate a shaft as a core within unit insertion space 3A. Screw section 3B which screw section 4B of the body covering 4 which carries out a postscript screws is formed in the lateral surface of opening of the front end of the body 3 of a sensor. Moreover, the switch mechanism 14 is formed near the opening of the body 3 of a sensor. The lead wire 16A and 16B connected to contact bowl 17for counter electrodes A of the body covering 4 and the body covering 4 later mentioned at the time of screwing and contact bowl 17B for operation poles, respectively is formed in the body 3 of a sensor.

[0022] Hereafter, the configuration of a switch mechanism 14 is explained using drawing 1 R> 1 and drawing 2 . First, piece of two pieces of bearings which carry out phase opposite 14A prepared so that this switch mechanism 14 might project in the lateral surface of the body 3 of a sensor, Pivotable support shaft 14B constructed among these two pieces of piece of bearing 14A, Stop pin 14D which engages with the front end side of drive lever 14C by which pars intermedia was supported pivotably by this pivotable support shaft 14B, and this drive lever 14C, and penetrates the side attachment wall of the body 3 of a sensor, and appears frequently in unit insertion space 3A, twisted coil spring 14E energized so that drive lever 14C may fall in front -- since -- the profile configuration is carried out. Moreover, guide hole 14G are formed in the anterior part of drive lever 14C along with the longitudinal direction. And guide shaft 14H are prepared in the upper limit of the above-mentioned stop pin 14D. These guide shaft 14H are being engaged free [sliding] to guide hole 14G. Stop pin 14D appears frequently to unit insertion space 3A in connection with the drive of drive lever 14C. At this time, along with guide hole 14G, guide shaft 14H slide and are guided. In addition, when this stop pin 14D inserts the sensor unit 2 in unit insertion space 3A of the body 3 of a sensor, it has the function to prevent that stop the front end of the counter electrode base 6, and the sensor unit 2 jumps out ahead.

[0023] Next, the configuration of the body covering 4 is explained using drawing 1 , drawing 2 , and drawing 5 . The body covering 4 is formed in the tubing configuration for example, with the resin ingredient which has insulation electrically. Contact bowl 17for counter electrodes A which the sensor unit 2 projects and connector 9for counter electrodes A and connector 11A for operation poles sometimes connect, respectively, and contact bowl 17B for operation poles are prepared in the interior of the body covering 4, and contact bowl 17for counter electrodes A and contact bowl 17B for operation poles are connected with the lead wire 16A and 16B of the body 3 of a sensor, respectively at the time of screwing with the body 3 of a sensor, and the body covering 4. moreover, opening of the body covering 4 front end -- the inside -- turning -- a collar -- flange 4A of a ** goes around and is formed. For this reason, as for the inside diameter of flange 4A, the inside diameter twist of the part of that back (back) is short. Moreover, screw section 3B of the above-mentioned body 3 of a sensor and screw section 4B to screw are formed in the opening wall of the back end of the body covering 4. In addition, in the condition of having screwed the screw sections of the body 3 of a sensor, and the body covering 4, it is set up so that the walls of the body 3 of a sensor and the body covering 4 may become flat-tapped. That is, except for the part of flange 4A of the body covering 4, and screw section 4B, the inside diameter of the body 3 of a sensor and the body covering 4 is set up identically. For this reason, where it contains the sensor unit 2 to unit insertion space 3A of the body 3 of a sensor and the body covering 4 is constructed on the body 3 of a sensor, even when the sensor unit 2 moves forward to max, in order that the front end side periphery section may **** the counter electrode base 6 to flange 4A, only a needle 5 projects from body covering 4 front face.

[0024] Here, the sensor unit 2 supplements with the configuration of the body covering 4 and the sensor unit 2 using drawing 2 which shows the condition of having moved forward to max. If stop pin 14D sinks from the internal surface of the body 3 of a sensor with actuation of a switch mechanism 14, the front face of the counter electrode base 6 of the unit sensor 2 **** to flange 4A according to the energization force of compression coil spring 13A. At this time, it prevents that stop pin 14D projects in

unit insertion space 3A again. That is, where the sensor unit 2 is extruded to flange 4A, it is set up so that the tip of stop pin 14D may contact the peripheral surface of the piston 13 for unit immobilization. Moreover, in the condition that the sensor unit 2 was extruded to flange 4A, connector 9A for counter electrodes of the sensor unit 2 is connected with contact bowl 17A for counter electrodes, and connector 11A for operation poles is connected with contact bowl 17B for operation poles. In addition, contact bowl 17A for these counter electrodes and contact bowl 17B for operation poles are formed with an electrode material, and are connected to lead wire 16A and 16B, respectively. These lead wire 16A and 16B is connected so that the body covering 4 may be penetrated from the outside of the body covering 4 and each end section may attain even a contact bowl. In addition, the other end of these lead wire 16A and 16B is connected to the electrical-potential-difference impression circuit 18 and the amperometry circuit 19 which carry out a postscript.

[0025] Next, it explains using the equal circuit which shows the circuitry of the blood sugar level gaging system in the biosensor 1 of this operation gestalt to drawing 7 . As shown in this drawing, the counter electrode 9 is connected to the electrical-potential-difference impression circuit 18 and the amperometry circuit 19 through connector 9for counter electrodes A, contact bowl 17for counter electrodes A, and lead-wire 16A. Moreover, the operation pole 11 (the enzyme fixed layer 12 is included) is connected to the electrical-potential-difference impression circuit 18 and the amperometry circuit 19 through connector 11for operation poles A, contact bowl 17for operation poles B, and lead-wire 16B. Furthermore, the amperometry circuit 19 is connected to the operation means 20 and the display means 21. In addition, the amperometry circuit 19 fills a sample between a counter electrode 9 and the operation pole 11 by the electrical-potential-difference impression circuit 18, and after impression of an electrical potential difference is started and carrying out predetermined time progress, it is set up so that a current value may be measured. Moreover, from electrical-potential-difference impression initiation, after [still longer] carrying out time amount progress, the electrical-potential-difference impression circuit 18 is set up so that electrical-potential-difference impression may be stopped.

[0026] Next, the operating instructions of the biosensor 1 of this operation gestalt, and an operation and actuation are explained. First, it fixes by inserting locating-lug 8A formed in the rear face of the operation pole base 8 of the sensor unit 2 in location notch 13B of the piston 13 for unit immobilization in which the sensor unit 2 was formed by the body 3 of a sensor. Since it is set up so that it may not rotate in the body 3 of a sensor as the piston 13 for unit immobilization was described above at this time, the sensor unit 2 fixed to the piston 13 for unit immobilization does not rotate, either. Subsequently, actuation which resists the energization force of compression coil spring 13A, and pushes in the sensor unit 2 in unit insertion space 3A is performed. When the back end of the piston 13 for unit immobilization is located ahead of stop pin 14D at this time, it is necessary to change stop pin 14D into the condition of sinking from the wall of the body 3 of a sensor, by what (for the back end section of drive lever 14C to be turned and pushed on the body 3 of a sensor) drive lever 14C is operated for. And if the front end of the counter electrode base 6 of the sensor unit 2 progresses behind stop pin 14D, since the energization force of twisted coil spring 14E is transmitted to stop pin 14D through drive lever 14C, it projects in unit insertion space 3A. Thus, when stop pin 14D projects in unit insertion space 3A, the front end of the sensor unit 2 is stopped by stop pin 14D, and it is set where it is prevented that the sensor unit 2 jumps out ahead.

[0027] Next, the case where the blood sugar level is measured using the biosensor 1 in the condition that the sensor unit 2 was set as described above is explained. First, opening of the body covering 4 of a biosensor 1 is applied to the skins, such as people's arm, and the back end section of drive lever 14C of a switch mechanism 14 is turned to the outer wall of the body 3 of a sensor, and is pressed down. Consequently, drive lever 14C rotates in the direction of the clockwise rotation in drawing, turns stop pin 14D to a way outside the body 3 of a sensor, and pulls up it. When the tip of stop pin 14D sinks from the wall of the body 3 of a sensor, the sensor unit 2 jumps out [in / in the front end side of the counter electrode base 6 / flange 4A] ahead according to the energization force of compression coil spring 13A.

At this time, only a needle 5 projects from opening of the body covering 4, pokes on the skin, and damages ******** and a hypodermic capillary. In connection with this, blood is introduced by capillarity in blood installation space 10A through blood installation way 5C of a needle 5, and inlet 6D of the counter electrode base 6. At this time, connector 9for counter electrodes A and connector 11A for operation poles are connected to contact bowl 17for counter electrodes A, and contact bowl 17B for operation poles, respectively, and the predetermined electrical potential difference is impressed from the electrical-potential-difference impression circuit 18 between the counter electrode 9 and the operation pole 11. Then, the current according to the glucose concentration in blood (minding a mediator, when the mediator is included), i.e., the blood sugar level, flows between a counter electrode 9 and the operation pole 11 through the dissolved oxygen by which the glucose in blood is contained in a lifting and the enzyme fixed layer 12 by operation of the enzyme fixed layer 12 in an enzyme reaction (reaction for which a glucose oxidizes) and which is an electron acceptor. After carrying out impression initiation of the electrical potential difference between an electrode 9 and 11 from the electrical-potential-difference impression circuit 18, the current value according to the above-mentioned blood sugar level can be measured by carrying out predetermined time progress and performing an amperometry in the amperometry circuit 19. In addition, since the current after going through fixed time amount after electrical-potential-difference impression is proportional to the glucose concentration of a certain density range, by inputting the proportionality coefficient into the operation means 20 beforehand, it can convert a current value into concentration and can display the blood sugar level on the display means 21. In addition, after measurement of such the blood sugar level is performed, and predetermined time passes further, electrical-potential-difference impression of the electrical-potential-difference impression circuit 18 stops.

[0028] Thus, what is necessary is to remove the body covering 4 from the body 3 of a sensor, and just to remove the sensor unit 2 from the piston 13 for unit immobilization subsequently, after measurement of the blood sugar level is completed. What is necessary is again, just to repeat the actuation which changed and described the sensor unit 2 above, when measuring the blood sugar level.

[0029] With this operation gestalt, since blood installation space 10A can set it as the predetermined volume, it is very little, and since it ends, and the amount of the blood which measurement takes does not have the problem of taking blood too much unfairly and can collect blood quantitatively (since the space volume of the path which introduces blood may be very small), a generating current can also be measured quantitatively and it can measure [regularity and] the blood sugar level for it with high precision. Moreover, since what is necessary is just to stab with a needle 5, the amount of the bleeding from the skin can be controlled. Moreover, with this operation gestalt, there is an advantage that it can carry out at installation, measurement, and one process of blood, without needing a blood extraction instrument. Furthermore, in order to introduce blood between a counter electrode 9 and the operation pole 11 using capillarity, there is an advantage that measurement can be ensured.

[0030] As mentioned above, although this operation gestalt was explained, various kinds of modification which is not limited to this and accompanies the summary of a configuration is possible for this invention. For example, although glucose oxidase was used as an enzyme with the above-mentioned operation gestalt, in order to perform density measurement, such as other components in blood, a metaphor lactic acid, alcohol, cholesterol, and a uric acid, it is easy to be natural also as a configuration which fixed other enzymes. Moreover, it is good also as a configuration which contains a mediator in the above-mentioned enzyme fixed layer 12. Furthermore, although considered as the cylindrical shape-like body 3 of a sensor with the above-mentioned operation gestalt, it is easy to be natural [a cross-section configuration] also as a configuration which is not a circle. The contact bowl which contacts each connector formed in the peripheral surface of the sensor unit 2 further again is good also as a configuration formed in the body [not the body covering 4 but] 3 side of a sensor.

[0031] Furthermore, although the electrode in connection with measurement of constituent concentration was two, a counter electrode 9 and the operation pole 11 (an enzyme fixed layer is included), with the

above-mentioned operation gestalt, it is good like the modification shown in drawing 7 also as a configuration which forms a reference electrode 22 near the operation pole 11 of the operation pole base 8. 22in drawing 7 A is the connector for reference electrodes which was formed in the peripheral surface of the operation pole base 8 and which was connected to the reference electrode 22. In addition, what is necessary is to form the contact bowl for reference electrodes in contact with connector 22A for reference electrodes in the body covering 4 side, and just to consider as the circuitry which added the reference electrode 22 in this modification, while adding a reference electrode 22 in this way. Other configurations are the same as that of the above-mentioned operation gestalt. Furthermore, as shown in drawing 8 , it can also consider as the configuration which added the enzyme non-holding operation pole 23 to the configuration of the modification shown in drawing 7 . Thus, it becomes possible to consider a configuration equipped with the enzyme non-holding operation pole 23, then the effect by the active jamming current by the uric acid, and to perform high measurement of precision more. Moreover, the active jamming current by an ascorbic acid etc. can also be controlled by using the operation pole 11 as the carbon containing platinum or a rhodium.

[Translation done.]

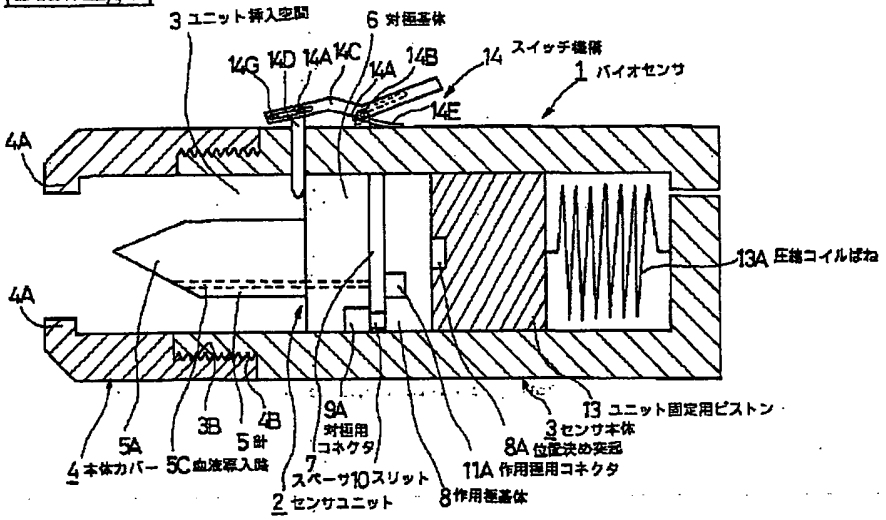
DESCRIPTION OF DRAWINGS

[Brief Description of the Drawings]
[Drawing 1] The cross-section explanatory view showing the condition of having stopped the sensor unit in the operation gestalt of the biosensor of this invention.
[Drawing 2] The cross-section explanatory view showing the condition of having canceled the stop of a sensor unit in the operation gestalt of the biosensor of this invention.
[Drawing 3] The decomposition perspective view of the sensor unit in this operation gestalt.
[Drawing 4] The sectional view of the sensor unit in this operation gestalt.
[Drawing 5] The cross-section perspective view of body covering in this operation gestalt.
[Drawing 6] The representative circuit schematic of this operation gestalt.
[Drawing 7] The decomposition perspective view showing the modification of this invention.
[Drawing 8] The decomposition perspective view showing the modification of this invention.
[Description of Notations]
1 Biosensor
2 Sensor Unit
3 Body of Sensor
4 Body Covering
5 Needle
9 Counter Electrode
9A The connector for counter electrodes
10A Blood installation space
11 Operation Pole
11A The connector for operation poles
12 Enzyme Fixed Layer
13 Piston for Unit Immobilization
13A Compression coil spring
14 Switch Mechanism
17A The contact bowl for counter electrodes
17B The contact bowl for operation poles

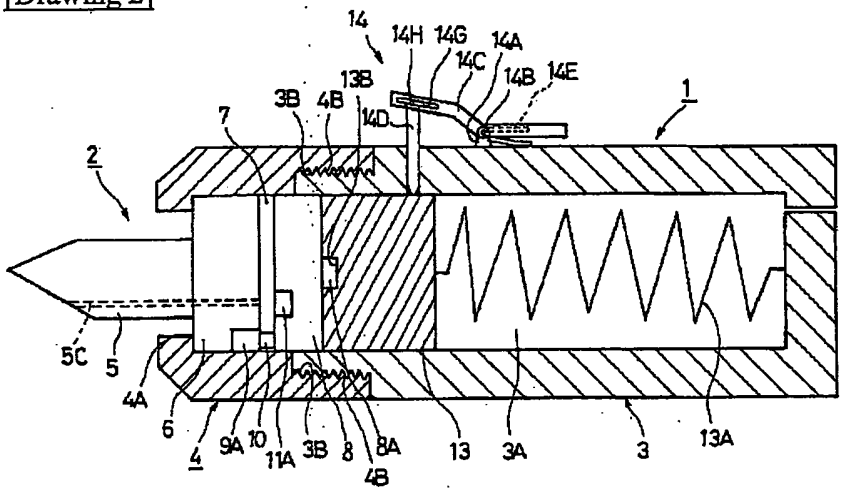
[Translation done.]

DRAWINGS

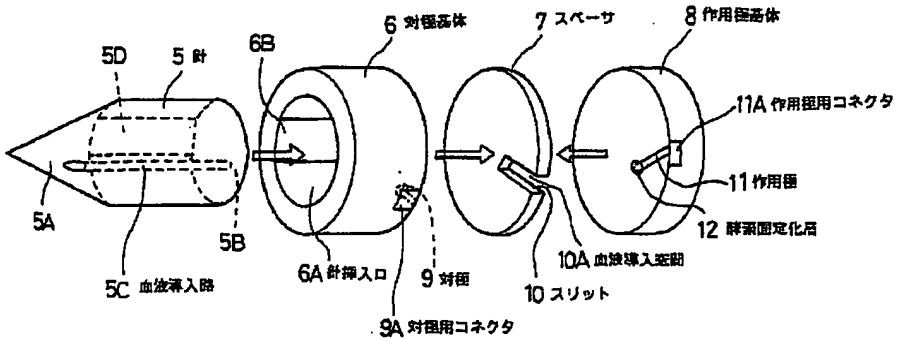
[Drawing 1]



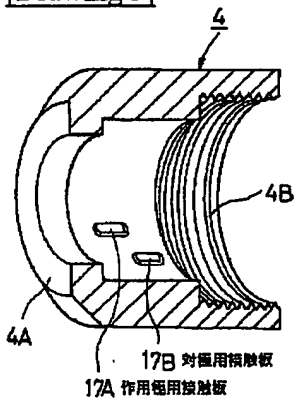
[Drawing 2]



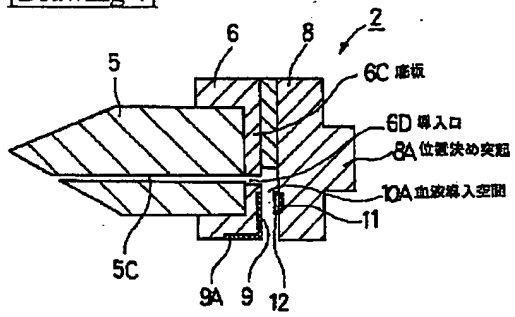
[Drawing 3]



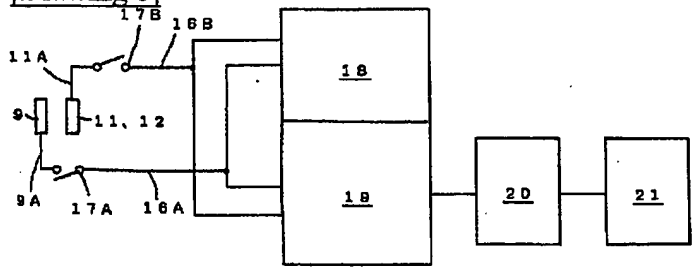
[Drawing 5]



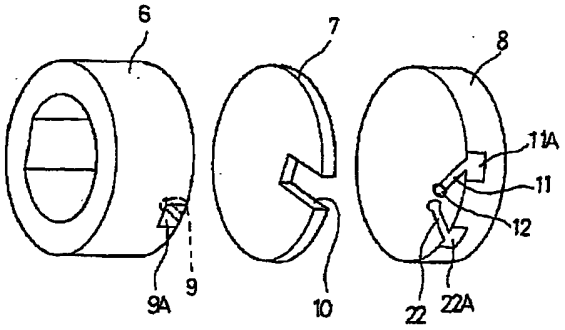
[Drawing 4]



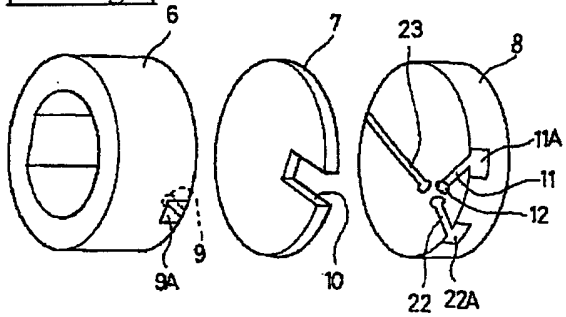
[Drawing 6]



[Drawing 7]



[Drawing 8]



[Translation done.]